

**Notice of Allowability****Application No.**

09/724,940

**Applicant(s)**

SCHENK, DALE B.

**Examiner**

Christopher J Nichols, Ph.D.

**Art Unit**

1647

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 24 June 2004.
2. ☒ The allowed claim(s) is/are 59-104.
3. ☒ The drawings filed on 25 November 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 8/27/02 6/7/02 10/1/03 8/5/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. The Response and Amendment filed 24 June 2004 has been received and entered in full.
2. The Preliminary Amendment filed 7 June 2002 has been received and entered in full.
3. The Declaration under 37 CFR 1.132 filed 24 June 2004 is sufficient to overcome the rejection of claims **31-37** based upon lack of enablement as set forth in the previous Office Action (24 December 2003).
4. All previous Objections and Rejections are hereby *withdrawn* and/or *moot* in view of Applicant's amendments.

## EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

In the Title:

ACTIVE IMMUNIZATION FOR TREATMENT OF ALZHEIMERS DISEASE

In the Claims:

Claims 1-58 (Cancelled)

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Claim 59 (Currently Amended) A method for prophylaxis of Alzheimer's disease in a subject, comprising administering to the subject a dosage of an immunogenic fragment of A $\beta$  (SEQ ID NO: 42) in a regime effective to produce an immune response comprising antibodies against A $\beta$ , wherein at least one amino acid of the immunogenic fragment is a D amino acid, thereby effecting prophylaxis of said disease, wherein the dose of the A $\beta$  is administered to the patient is at least 50  $\mu$ g.

Claim 60 (Previously Presented) The method of claim 59, further comprising administering an adjuvant with said peptide.

Claim 61 (Currently Amended) The method of claim 60, wherein said adjuvant is selected from the group consisting of STIMULON QS-21, 3 De-O-acylated-monophosphoryl lipid A ~~De-O-acylated-monophosphoryl lipid A~~, and alum.

Claim 62 (Previously Presented) The method of claim 59, wherein said A $\beta$  fragment is A $\beta$  1-3.

Claim 63 (Previously Presented) The method of claim 59, wherein said A $\beta$  fragment is A $\beta$  1-4.

Claim 64 (Previously Presented) The method of claim 59, wherein said A $\beta$  fragment is A $\beta$  1-5.

Claim 65 (Previously Presented) The method of claim 59, wherein said A $\beta$  fragment is A $\beta$  1-6.

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Claim 66 (Previously Presented) The method of claim 59, wherein said A $\beta$  fragment is A $\beta$  1-7.

Claim 67 (Previously Presented) The method of claim 59, wherein said A $\beta$  fragment is A $\beta$  1-12.

Claim 68 (Previously Presented) The method of claim 59, wherein said A $\beta$  fragment is A $\beta$  13-28.

Claim 69 (Previously Presented) The method of claim 59, wherein said A $\beta$  fragment is A $\beta$  25-35.

Claim 70 (Previously Presented) The method of claim 59, wherein said A $\beta$  fragment is A $\beta$  33-42.

Claim 71 (Previously Presented) The method of claim 62, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 72 (Previously Presented) The method of claim 63, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 73 (Previously Presented) The method of claim 64, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

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Claim 74 (Previously Presented) The method of claim 65, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 75 (Currently Amended) The method of claim 66, wherein said A $\beta$  fragment is linked to a carrier ~~molecule~~5 molecule to form a conjugate.

Claim 76 (Previously Presented) The method of claim 67, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 77 (Previously Presented) The method of claim 68, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 78 (Previously Presented) The method of claim 69, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 79 (Previously Presented) The method of claim 70, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 80 (Previously Presented) The method of claim 59, wherein the subject has a known genetic risk of Alzheimer's disease.

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Claim 81 (Previously Presented) The method of claim 59, wherein said subject is a human being.

Claim 82 (Currently Amended) A method for treating Alzheimer's disease in a subject, comprising administering to the subject a dosage of an immunogenic fragment of A $\beta$  (SEQ ID NO: 42) in a regime effective to produce an immune response comprising antibodies against A $\beta$ , wherein at least one amino acid of the immunogenic fragment is a D amino acid, thereby treating said disease, wherein the dose of the A $\beta$  administered to the patient is at least 50  $\mu$ g.

Claim 83 (Currently Amended) The method of claim ~~65~~ 82, further comprising administering an adjuvant with said peptide.

Claim 84 (Currently Amended) The method of claim ~~60~~ 83, wherein said adjuvant is selected from the group consisting of STIMULON QS-21, 3 De-O-acylated-monophosphoryl lipid A ~~De-O-acylated-monophosphoryl lipid A~~, and alum.

Claim 85 (Currently Amended) The method of claim ~~59~~ 82, wherein said A $\beta$  fragment is A $\beta$  1-3.

Claim 86 (Currently Amended) The method of claim ~~59~~ 82, wherein said A $\beta$  fragment is A $\beta$  1-4.

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Claim 87 (Currently Amended) The method of claim ~~59~~ 82, wherein said A $\beta$  fragment is A $\beta$  1-5.

Claim 88 (Currently Amended) The method of claim ~~59~~ 82, wherein said A $\beta$  fragment is A $\beta$  1-6.

Claim 89 (Currently Amended) The method of claim ~~59~~ 82, wherein said A $\beta$  fragment is A $\beta$  1-7.

Claim 90 (Currently Amended) The method of claim ~~59~~ 82, wherein said A $\beta$  fragment is A $\beta$  1-12.

Claim 91 (Currently Amended) The method of claim ~~59~~ 82, wherein said A $\beta$  fragment is A $\beta$  13-28.

Claim 92 (Currently Amended) The method of claim ~~59~~ 82, wherein said A $\beta$  fragment is A $\beta$  25-35.

Claim 93 (Currently Amended) The method of claim ~~59~~ 82, wherein said A $\beta$  fragment is A $\beta$  33-42.

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Claim 94 (Currently Amended) The method of claim 62 85, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 95 (Currently Amended) The method of claim 63 86, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 96 (Currently Amended) The method of claim 64 87, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 97 (Currently Amended) The method of claim 65 88, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 98 (Currently Amended) The method of claim 66 89, wherein said A $\beta$  fragment is linked to a carrier ~~molecule~~5 molecule to form a conjugate.

Claim 99 (Currently Amended) The method of claim 67 90, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 100 (Currently Amended) The method of claim 68 91, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.



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Claim 101 (Currently Amended) The method of claim ~~69~~ 92, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 102 (Currently Amended) The method of claim ~~70~~ 93, wherein said A $\beta$  fragment is linked to a carrier molecule to form a conjugate.

Claim 103 (Currently Amended) The method of claim ~~59~~ 82, wherein the subject has a known genetic risk of Alzheimer's disease.

Claim 104 (Currently Amended) The method of claim ~~59~~ 82, wherein said subject is a human being.

6. Authorization for this examiner's amendment was given in a telephone interview with Rosemaire Celli on 22 September 2004.

### *Summary*

7. Claims **58-104** are hereby allowed.

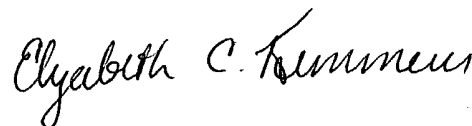
8. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).



CJN  
September 23, 2004

ELIZABETH KEMMERER  
PRIMARY EXAMINER